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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,408	02/21/2002	Lars Abrahmsen	13425-053001	1557
26161	7590	03/03/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			PAK, YONG D	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/081,408

Applicant(s)

ABRAHMSEN ET AL.

Examiner

Yong D. Pak

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 January 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 12 January 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1, 4, 7 and 9-24.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____

13. ☐ Other: _____.

ADVISORY ACTION

Response to Arguments

The amendment filed on January 12, 2006 under 37 CFR 1.116 in reply to the final rejection has been considered and has been entered but is not deemed to place the application in condition for allowance because: the amendment and request for consideration does not overcome the rejection of claims 1, 4, 7 and 9-24 under 35 U.S.C. 103(a), as discussed below.

Claims 1, 4, 7 and 9-24 are pending and are under consideration.

Claim Rejections - 35 USC § 103

Claims 1, 4, 7, 9-10, 15, 17-19 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al., Huston et al. and Tudyka et al.

In response to the previous Office Action, applicants have traversed the above rejection.

Applicants argue that Smith contains no description whatsoever of a soluble form of SSAO. Examiner respectfully disagrees. While Smith does not teach an isolated soluble form of the enzyme, Smith does teach that the soluble form of SSAO lacks the membrane spanning portion of the wild-type SSAO and identifies the transmembrane domain as being between residues 5-27 (Figure 1, page 20 and page 21).

Applicants also argue that the claims are not obvious because the claimed nucleic acid provides a solution to the long-felt but unsatisfied need of a means for purifying to homogeneity and in high amounts a recombinant human soluble SSAO,

wherein the claimed nucleic acid permits the recombinant production of milligram quantities of pure, soluble and biologically active human SSAO. Examiner notes that the claims do not recite said limitation that the nucleic acid permits for purifying a recombinant human soluble SSAO to homogeneity and in high amounts. Rather, the claims are drawn to a polynucleotide encoding a fusion protein comprising a signal peptide, soluble human SSAO, fusion partner, protease cleavage site and optionally one or more spacer amino acids, with no recitation of the homogeneity or the yield of the encoded SSAO enzyme.

Applicants also argue that there is objective evidence that the invention fulfills a need that existed in the art for a long period of time without solution and therefore, the claims are non-obvious. When any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under this section. No such oath or declaration has been filed. Nevertheless, Examiner has reviewed the articles mentioned by applicants (Exhibits C and D).

Applicants argue that Holt et al. (Exhibit C) and Elmore et al. (Exhibit D) provide evidence of the long-felt but unsatisfied need of a means for purifying high amount of a recombinant soluble SSAO. Examiner respectfully disagrees. First, the claims do not recite a limitation for a "means for purifying high amount of a recombinant soluble SSAO". Second, neither of the references provides evidence of the long-felt but unsatisfied need of a means for purifying high amount of a recombinant soluble SSAO. Holt et al. teaches that SSAO (membrane bound SSAO) "has proved impossible to

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purify to homogeneity in sufficient yield to permit cofactor identification(abstract).

Contrary to applicants arguments, Holt et al. does not provide evidence of a long felt need to purify soluble SSAO, but that sufficient purification of membrane bound SSAO for its cofactor identification is difficult. Elmore et al. also fails to provide evidence of the long felt need. Contrary to applicants' argument, instead of providing evidence of a long felt need of a means for purifying high amounts of recombinant human soluble SSAO, Elmore et al. in fact provides a solution for purifying soluble mammalian copper-containing amino oxidases and therefore human soluble SSAO. Elmore et al. teaches purification of a mammalian diamine oxidase, which are soluble copper-containing amino oxidases (page 566-561).

Applicants also argue that Elmore et al. teaches purification of the first successful overexpression of any mammalian copper-containing amine oxidase, demonstrating the difficulty that person of skill in the art had experience in expressing and purifying copper-containing amine oxidases. If this is the case, then applicants argument that the claims provide a solution for a long-felt need is invalid because MPEP 716.04 states that:

"Establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors.

First, the need must have been a persistent one that was recognized by those of ordinary skill in the art.

Second, the long-felt need must not have been satisfied by another before the invention by applicant.

Third, the invention must in fact satisfy the long-felt need."

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In the instant case, the long-felt need has been satisfied by Elmore et al. before filing of the instant invention. Elmore et al. teaches purification of a diamine oxidase, a soluble copper-containing amine oxidase (page 566-561). Therefore, Elmore et al. does indeed provide evidence of expression and purification of a recombinant soluble mammalian copper-containing amino oxidase prior to the present application. Therefore applicant's claim of a long-felt need for a long period of time without solution is invalid.

Further, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem (MPEP 716.04).

Therefore, as discussed previously, one of ordinary skill in the art would have had a reasonable expectation of success of making a polynucleotide encoding a fusion protein since the individual proteins incorporated into the fusion proteins are well known in the art and Huston et al. and Tudyka et al. in combination teach detailed steps in making a successful fusion protein and methods of purifying the fusion protein and ultimately the protein of interest.

Hence the rejection is maintained.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al., Huston et al. and Tudyka et al. and Zambidis et al.

In response to the previous Office Action, applicants have traversed the above rejection. Applicants argue that since Zambidis et al. does not cure the deficiencies in Smith, Huston, and Tudyka detailed above, the references do not render obvious the nucleic acid of claim 11. Examiner respectfully disagrees. As discussed above, since

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applicants argument that there're is a long-felt need in the art for a means of producing soluble recombinant human SSAO and the long-felt need was not fulfilled prior to the fling of the present application is unfounded, the rejection is maintained.

Claims 12-13 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al., Huston et al. and Tudyka et al. and Brenda Enzyme Database.

In response to the previous Office Action, applicants have traversed the above rejection. Applicants argue that since Brenda does not cure the deficiencies in Smith, Huston, and Tudyka detailed above, the references do not render obvious the nucleic acid of claim 1. Examiner respectfully disagrees. As discussed above, since applicants argument that there're is a long-felt need in the art for a means of producing soluble recombinant human SSAO and the long-felt need was not fulfilled prior to the fling of the present application is unfounded, the rejection is maintained.

Allowable Subject Matter

Claims 14 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

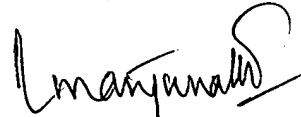
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax

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phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner 1652

A handwritten signature in black ink, appearing to read 'Manjunath Rao', with a stylized flourish at the end.

Manjunath Rao
Primary Patent Examiner 1652